

Food and Drug Administration Rockville MD 20857

MAY 17 1999

The Honorable John M. McHugh House of Representatives Washington, D.C. 20515-3224

Dear Mr. McHugh:

Thank you for your letter of March 16, 1999 on behalf of Ms. Colleen Chadwick concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation.

The 1997 FDA Modernization Act (PL 105-115) states that "[n] o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients . . "FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation (21 CFR 179), are enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take.

We have forwarded Ms. Chadwick's correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of irradiated foods will take into account all of the data and information received.

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Because your constituent may be concerned about irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this responds to your concerns.

Sincerely,

Jane F. Kurly for Melinda K. Plaisier

Interim Associate Commissioner for Legislative Affairs

Enclosures

cc: Dockets Management Branch (98N-1038)

JOHN M. McHUGH

24TH DISTRICT, NEW YORK

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Congress of the United States

House of Representatives

2441 Rayburn House Office Building Washington, DC 20515-3224

March 16, 1999

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Ms. Diane E. Thompson Assoc. Commissioner For Legislative Affairs Food and Drug Administration 5600 Fishers Lane, Room 1555 Rockville, Maryland 20857

Dear Ms. Thompson:

A constituent of mine, Ms. Colleen Chadwick of Johnstown, New York, has contacted me in regard to the labeling of irradiated food and proposals put forth by the Food and Drug Administration in Docket No. 98N-1038, "Irradiation in the Production, Processing, and Handling of Food."

Ms. Chadwick urges that the FDA retain the current labeling law, the current terminology of "treated with radiation" or "treated by irradiation." At the very least, she urges that these foods should be prominently labeled and that all irradiated components of a food should be identified. Ms. Chadwick further believes that, regardless of whether the FDA has approved irradiation as safe, it remains a new technology with no long-term human feeding studies.

I would appreciate my constituent's views being taken into consideration and being provided with a basis for reply to her on this important issue.

Thank you for your assistance.

Sincerely yours,

John M. McHugh Member of Congress

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